

**METHOD FOR DETECTING HEPATITIS B ANTIGEN IN THE PRESENCE
OF ALUMINIUM HYDROXIDE**

The present invention relates to methods and kits for the detection of antigens.

The detection and/or quantification of certain antigens may be required after the antigen has been formulated in some way with additional components. For example, in the case of certain hepatitis B vaccines, the Hepatitis B surface antigen is formulated with aluminium hydroxide. Such formulation with aluminium hydroxide, however, provides problems for the quantification of the antigen component, as the presence of aluminium hydroxide appears in some way (either directly or indirectly) to interfere with the binding of antigen to antibodies in antibody based (eg ELISA) detection methods.

There is still a need to develop assay systems that avoid the problems of interference with aluminium hydroxide in the formulation.

The present invention addresses this need.

In a first aspect the present invention relates to a method for the detection of an antigen in a sample, the antigen being in a combination with aluminium hydroxide, the method comprising the steps of:

- 1 contacting the sample with an immunoglobulin, or fragment thereof, in the context of a solid support and in the presence of a basic buffer, to allow binding of the antigen in the sample to the immunoglobulin or fragment thereof;
 - 2 adding a blocking agent; and
 - 3 detecting the binding of antibody to the antigen,
- wherein the steps are performed in that order but not necessarily consecutively.

The invention also relates to a kit for the detection of an antigen in combination with aluminium hydroxide, the kit comprising an instruction leaflet detailing the method